REMARKS

THE CLAIM AMENDMENTS

Claim 1 has been amended to recite that the matrix of the dosage form is comprised of at least two biocompatible, hydrophilic polymers, one of which is a high molecular weight polyalkylene oxide that enhances swelling in the dosage form and the other of which is a low molecular weight polyalkylene oxide that enhances erosion in the dosage form. Support for the amendment to claim 1 is found in the specification at *inter alia*, the paragraphs at page 21, line 20 to page 22, line 3, and Examples 1 and 2, both of which describe dosage forms with at least two biocompatible, hydrophilic polymers.

With the change to claim 1, claims 2, 6-17, and 22 have been amended to change the recitation of "at least one" to --at least two-- in reference to the biocompatible, hydrophilic polymers. Claim 1 has also been amended to remove the claim limitation added in the prior amendment filed on December 27, 2005.

Claims 50-53, 55, and 56 have been canceled.

No new matter has been added to the application with the claim amendments set forth herein.

THE INDEFINITENESS REJECTION

Claims 1-37, 39, 40, and 45-56 stand rejected under 35 U.S.C. § 112, first paragraph, as indefinite. The Examiner asserts that the recitation added to claim 1 in the prior amendment is new matter.

In response, applicants would like the Examiner to take notice that independent claim 54 (as well as pre-cancellation claims 50-53, 55, and 56) were not amended to incorporate the limitation that was added to claim 1 in the prior rejection; accordingly, claims 50-56 should not have been included in this rejection.

With respect to the substance of the Examiner's rejection, applicants would like to state for the record that they disagree with the Examiner; the specification clearly provides support for a recitation that the dosage form exceeds 1 cm. Notwithstanding the foregoing, with the amendment to claim 1 as set forth above, this rejection is rendered moot for all applicable claims; accordingly, applicants request withdrawal of this rejection.

THE ANTICIPATION REJECTION OVER SHELL ET AL. (SHELL 1)

Claims 1-9, 12-16, 18-23, 26-34, 36-40, and 45-55 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shell et al. (USPN 5,972,389; "Shell 1"). This rejection is moot for canceled claims 6, 7, 50-53, 55, and 56 and is respectfully traversed for the remaining cited claims.

Shell 1 teaches a gastric-retentive dosage form composed of a plurality of particles of a solid-state drug dispersed within a polyethylene oxide polymer (col. 1, l.64, to col. 2, l.2; col. 7, ll. 59-60). Despite the Examiner's inclusion of claims pre-cancellation claims 50 and 51 and pending claims 54 and 55 in this rejection, Shell 1 does ***not*** teach or suggest that the dosage form disclosed therein may include more than one polyethylene oxide polymer. Indeed, a review of Shell 1 clearly indicates that the patent only contemplates that the active agent is incorporated into a single hydrophilic polymer (*see*, col. 1, l.67, to col. 2, l.2; col. 2, ll. 19-20; col. 2, ll. 58-59; Figures 1-3 and col. 3, ll. 6-14; Example 3, col. 11, l.66, to col. 12, l.1; Example 4 col. 12, ll. 31-34; Example 5, ll. 17-19; and Example 7, col. 14, ll. 13-16 (in this example, each pellet contains an active agent in a matrix of one polyethylene glycol)).

As noted above, independent claim 1 has been amended to recite that the dosage form includes at least two polymers. Pending claims 2-5, 8, 9, 12-16, 18-23, 26-34, 36-40, and 45-49 all depend from claim 1. Independent claim 54 is directed to a dosage form with a matrix comprised of a polyethylene oxide admixed with polyethylene oxide-co-propylene oxide.

Because Shell 1 does not teach or suggest using more than one polyethylene oxide polymer in the dosage form described therein, it follows that Shell 1 does not anticipate the claimed invention. In view of the foregoing, applicants request withdrawal of this rejection.

THE ANTICIPATION REJECTION OVER SHELL (SHELL 2)

Claims 1-7, 10, 12, 17-23, and 45-49 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shell (USPN 5,007,790; "Shell 2). This rejection is moot for canceled claims 6, 7, and 10 and is respectfully traversed for the remaining cited claims.

Shell 2 teaches a drug dosage form composed of an oral dosage form composed of a plurality of solid particles composed of a solid state drug dispersed within a hydrophilic, water swellable polymer (col. 1, ll. 56-58). Examples of hydrophilic polymers contemplated under Shell 2 include gelatin, albumin, sodium alginate, caboxymethyl cellulose, polynvinyl alcohol, and chitin (col. 3, ll. 11-14; Example 1 (uses gelatin); Example 2 (uses gelatin); Example 3 (uses gelatin); Example 4 (uses sodium alginate); Example 5 (uses sodium alginate); Example 6 (uses sodium alginate)). Like Shell 1, Shell 2 does ***not*** teach or suggest that more than one polymer may be used in the dosage form described therein. Further Shell 2 also does not contemplate polyalkylene oxides as hydrophilic, water swellable polymers that may be used to formulate the dosage forms described therein.

As noted above, independent claim 1 has been amended to recite that the dosage form includes at polyalkylene oxide polymers. Claims 2-7 10, 12, 17-23, and 45-49 all depend from claim 1. Because Shell 2 does not teach or suggest using more than one hydrophilic polymer in the dosage form described

therein, it follows that Shell 2 does not anticipate the claimed invention. In view of the foregoing, applicants request withdrawal of this rejection.

THE ANTICIPATION REJECTION OVER UEMURA ET AL.

Claims 1-7, 10, 17-22, and 39 stand rejected under 35 U.S.C. § 102(b) as anticipated by Uemura et al. (USPN 4,695,467). This rejection is moot for canceled claims 6, 7, and 10 and is respectfully traversed for the remaining cited claims.

Uemura et al. teaches a sustained release tablet composed of a drug, a disintegrating agent, and a water soluble polymer, which may be a cellulose derivative such as hydroxypropylmethylcellulose, a water soluble polymer such as polyethylene oxide, or a polysaccharide (col. 2, ll. 65-66; col. 3, ll. 30-38). Uemura et al. does ***not*** teach or suggest that of the polymers disclosed therein, one is selected to enhance swelling while the other is selected to enhance erosion. Claims 2-7, 10, 17-22, and 39 all depend from claim 1. Because Uemura et al. does not teach or suggest using the polymers described therein to enhance swelling and erosion of the dosage form as claimed, it follows that Uemura et al. does not anticipate the claimed invention. In view of the foregoing, applicants request withdrawal of this rejection.

THE OBVIOUSNESS REJECTION OVER PATEL ET AL.

Claims 1, 6-11, 23-25, 34, and 35 stand rejected under 35 U.S.C. § 102(e)/103(a) as anticipated by or obvious over Patel et al. (USPN 6,248,363). This rejection is moot for canceled claims 6, 7, 10, and 11 and is respectfully traversed for the remaining cited claims.

Patel et al. teaches a pharmaceutical delivery system composed of a solid carrier that includes a substrate and an encapsulation coat on the substrate (col. 2, ll. 58-60), wherein the encapsulation coat can include different combinations of pharmaceutical active ingredients, hydrophilic surfactants, lipophilic surfactants, and triglycerides (col. 4, ll. 10-12).

The Examiner cites Patel et al. at pages 8 and 9 of the Office Action under reply for the teaching of an active agent incorporated in zein or a xanthan gum matrix.

Claims 8, 9, 23-25, 34, and 35 all depend from claim 1. With the amendment to claim 1 to be directed to at least two polyalkylene oxides and the cancellation of claims 6 and 11, this rejection is rendered moot. In view of the foregoing, applicants request withdrawal of this rejection.

CONCLUSION

With this paper, each of the Examiner's rejections have been fully addressed and overcome. Because there will be no outstanding issues for this matter upon entry of this paper, applicants respectfully request withdrawal of all claim rejections and passage of this application to issue.

Any questions regarding this paper or the application in general may be addressed to the undersigned attorney at 650-251-7713 or kcanaan@mintz.com.

Respectfully submitted,

By: 

Karen Canaan, Esq.
Registration No. 42,382
MINTZ LEVIN
1400 Page Mill Road
Palo Alto, CA 94304

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